PPAC2 Synopsis

Trial title	The impact of postoperative **P**acking of **P**erianal **A**bscess **C**avities: a multicentre randomised controlled trial
Short title	PPAC2 (PPAC '1' was the feasibility study)
Sponsor	Manchester University NHS Foundation Trust
CI	Professor James Hill, Consultant General and Colorectal Surgeon
Phase	III
Sample size	526 UK patients from approx. 60 sites
Duration	Each patient will be on trial for 6 months following their perianal abscess operation. Follow up data for months 7-12 will be collected via HES.
Outcomes	The aim of this Randomised Controlled Trial is to compare internal wound packing to no packing in postoperative management following incision and drainage of perianal abscess Primary: The primary outcome measure is pain intensity. Patients will be asked to record wound-related pain (worst pain during previous 24 hours) using a 100mm Visual Analogue Score (VAS). The primary outcome will be the mean score over the first 10 post-operative days. Secondary: • Pain at dressing change (before, during and after) • Health related quality of life (measured using EQ-5D™ descriptive system) • Health Utility (measured using EQ-5D™ descriptive system) • Patient satisfaction with wound management (measured using a five point Likert scale) • Rate of wound healing (complete epithelialization at four and eight weeks)

	• Post-operative fistula-in-ano • Abscesses recurrence (after healing) • Chronic post-surgical pain • Resource use (including dressing, health professional contact time, hospital admission, time to return to work or normal function) • Cost (applied to resource use data above) • Patient Global Assessment of the method of pain control • Flagyl use
Eligibility	<u>Inclusion criteria:</u> 1. Aged 18 or over 2. Undergoing surgical incision and drainage of a primary perianal abscess <u>Exclusion criteria:</u> 1. Suspected inflammatory bowel disease 2. Fournier's Gangrene 3. Horseshoe (bilateral) abscess
Consent	• Consent will be obtained pre-operatively or post-operatively
Procedure	• Patients will report to hospital in an emergency setting. • All patients will initially have their wound packed intra-operatively • Randomisation will occur after the incision and drainage procedure • Packing Arm – Perianal abscess cavity will continue to be packed by community nurses as per local practice • Non-packing arm – At first dressing change the packing will be removed and an external dressing applied to their perianal abscess cavity • QoL questionnaires, VAS scales and Brief Pain Inventory forms will be completed at various time-points by the patients • Return to work status will be established will be established via telephone consultations.

	• Patients will receive an outpatient review at weeks 4, 8 (only if not healed at 4 weeks) and 26 to assess: o Return to work status o Abscess recurrence o Development of fistula-in-ano o Wound healing progress o Establishment of duration of packing (if applicable) o Occurrence of SAEs
Packings and dressings	The treatments being used in PPAC2 are all existing, commercially available, marketed products which are licensed and CE marked. Participating Trusts can select the packing and dressings of their choice. This will allow practitioners to use the dressing type that they are most familiar with.